

AMENDMENTS TO THE CLAIMS:

Claim 1 (Currently Amended): A process for the purification of olanzapine characterized in that said process comprises the following steps:

a) mixing olanzapine with an organic acid in an organic solvent or a mixture of organic solvents to form an olanzapine acid addition salt,

b) precipitating and isolating the ~~olanzapine~~ olanzapine acid addition salt and,

c) transformation of the olanzapine acid addition salt to olanzapine, wherein the transformation step comprises the following substeps:

i) dissolving an acid addition salt of olanzapine in water to form an aqueous solution thereof,

ii) adjusting the pH of the obtained aqueous solution to about 8-10,

iii) extracting olanzapine from the aqueous phase to an organic solvent phase and

iv) isolating the acid addition salt of olanzapine from the organic solvent phase by concentrating the solution to form olanzapine salt crystals therein and separation of the crystals of the aforementioned salt of olanzapine therefrom.

Claim 2 (Currently Amended): The process according to claim 1 wherein the organic acid in step (a) is selected from the group consisting of one or more sulfonic acids or one or more carboxylic acids.

Claim 3 (Currently Amended): The process according to claim 2 wherein the one or more carboxylic acids ~~is~~ are selected from the group consisting of one or more of fumaric acid and benzoic acid.

Claim 4 (Currently Amended): The process according to claim 1 wherein the organic solvent in step (a) is selected from the group consisting of one or more of tetrahydrofuran, acetone, dimethylformamide and acetonitrile.

Claim 5 (Previously Presented): The process according to claim 1 wherein the mixture of organic solvents in step (a) is a mixture of tetrahydrofuran with at least one polar solvent.

Claim 6 (Currently Amended): The process according to claim 5 wherein said polar solvent is selected from the group consisting of one or more of dimethylformamide, dimethylacetamide, N-methylpyrrolidone, 1,3-dimethyl-3,4,5,6-tetrahydro-2(1H)-pyrimidinone, ~~1,3-dimethyl-2-imidazolidinone~~ 1,3-dimethyl-2-imidazolidinone, tetramethylurea, dimethyl sulfoxide, sulfolane, acetone and acetonitrile.

Claims 7-21 (Cancelled)

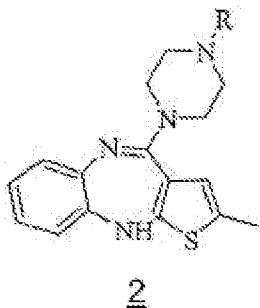
Claim 22 (Currently Amended): A process for the preparation of olanzapine in the form of an acid addition salt characterized in that said process comprises the following steps:

- a) reacting 4-amino-2-methyl-10H-thieno[2,3-b][1,5]benzodiazepine hydrochloride ~~is reacted~~ with N-methylpiperazine to yield olanzapine and
- b) transforming the obtained olanzapine ~~is transformed~~ to an acid addition salt thereof, wherein the transformation step comprises the following substeps:
 - i) diluting the obtained reaction mixture with water,
 - ii) extracting the diluted reaction mixture with an organic solvent, wherein the organic solvent is selected from the group consisting of ketones, chlorinated hydrocarbons, and mixtures thereof,
 - iii) evaporating the organic phase and diluting the residue with a second solvent to obtain a solution containing the residue,
 - iv) adding an organic acid to the solution containing the residue to precipitate olanzapine acid addition salt therefrom and
 - v) isolating precipitated olanzapine acid addition salt by formation and separation of crystals from the solution.

Claim 23 (Cancelled).

Claim 24 (Currently Amended): A process for the preparation of olanzapine in the form of an acid addition salt characterized in that said process comprises the following steps:

- a) N-desmethyloanzapine is reacted with a methylating agent to yield olanzapine,
b) the obtained reaction mixture is diluted with water and acidified with an acid,
c) to the reaction mixture, ~~[[an]]~~ a chlorinated organic solvent is added ~~and the phases are to provide separable aqueous and organic phases which are then~~ separated,
d) the obtained aqueous ~~water~~ phase is neutralized and olanzapine is extracted therefrom with ~~[[an]]~~ a chlorinated organic solvent to obtain the organic solvent phase and
e) an organic acid or substituted organic acid or an organic acid derivative of formula RX; wherein R represents an organic radical ~~such as acetyl, propionyl, chloroacetyl~~ and X is selected from a group of Cl, Br or I; or an organic acid anhydride; is added to the organic phase to form a N substituted N-desmethyloanzapine N-desmethyloanzapine derivative of formula 2



- f) the obtained organic solvent phase is optionally evaporated and the residue is diluted with a second organic solvent,
- g) an organic acid is added either to the obtained diluted solution containing the second organic solvent and residue therein or directly to the olanzapine extract from said extraction in step (d) and
- h) precipitated olanzapine acid addition salt is isolated by separation of the crystals.

Claim 25 (Cancelled)

U.S. Application No. 10/598,816

Claim 26 (Currently Amended): The process according to claim ~~[[25]]~~ 24 wherein said chlorinated organic solvent is methylene chloride.

Claim 27 (Original): The process according to claim 24 wherein the organic solvent in steps (c) and (d) is methylene chloride and said second solvent in step (f) is methanol.

Claims 28-34 (Cancelled)

Claim 35 (Currently Amended): Olanzapine prepared according to the processes disclosed in claim 1 characterized in that the detectible N-desmethyloanzapine content, if any, in the final product of olanzapine is less than 0.1 %.

Claim 36 (Currently Amended): Olanzapine prepared according to the-processes disclosed in claim 1 that contains a detectible amount, if any, of less than 0.05 % of piperazine 1,4-bis-4-yl-(2-methyl)-10H-thieno-[2,3-b][1,5]benzodiazepine.

Claims 37-43 (Cancelled)